April 13, 2006

Lynne Jones
Metal Carboxylates Coalition
SOCMA
1850 M Street NW, Suite 700
Washington, DC 20036

Dear Ms. Jones,

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for the revised Aluminum Stearates Category posted on the ChemRTK HPV Challenge Program Web site on August 27, 2004. I commend the Metal Carboxylates Coalition of SOCMA for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA has reviewed the submission and concludes that no further testing is necessary. However, some clarification and additional discussion are needed.

Category Justification. Aluminum distearate (CAS No. 300-92-5) and aluminum tristearate (CAS No. 637-12-7) are closely related and adequately supported as a category.

Bioavailability Discussion. On May 21, 2003, EPA commented that the original test plan (which covered a larger, more diverse proposed category of salts) did not adequately support the statement by the submitter that the bioavailability of metal carboxylate salts (affecting environmental fate, mammalian toxicity, and aquatic toxicity) would be equivalent to that of the separate metal ions and organic acids. These EPA comments have not been adequately addressed in the revised test plan submission and the original EPA comments on this issue still apply. Further, the draft study by Stopford et al., 2002, used to support the discussion of dissociation constants, was published in 2003 [Stopford W., Turner J, Cappellini D, and Brock T (2003) Bioaccessibility testing of cobalt compounds. J. Environ. Monit. 5(4): 675-680] and should be updated in the revised test plan. However, it is still not clear how the results presented by Stopford et al. for cobalt(II) would necessarily be relevant to aluminum(III). Furthermore, it would be difficult to predict, without experimental evidence, whether the free acid, metal ion, or metal complex forms would predominate under particular physiological or environmental conditions. The statement that metal chlorides are similar to or more bioavailable than the corresponding metal carboxylate salts may be true for cobalt(II) compounds, as outlined by Stopford et al., but may not hold for aluminum. In aqueous solution at neutral pH, Co(II) may be soluble and bioavailable owing to the lower log Kow value of carbon content present, but it is likely that the Al(III) ion will not be soluble or bioavailable because the log Kow of 22.7 (calculated for aluminum tristearate) is far too high (so that discussion in terms of a lack of bioavailability may be more appropriate.). EPA suggests that the submitter present a technical discussion, in the test plan, addressing the dissociation of the aluminum stearates with experimental data on the sponsored substances, if available.

Physicochemical Properties. For the boiling point, the submitter needs to report in the robust summaries that both aluminum stearate salts undergo decomposition upon heating and report the decomposition temperatures if available. Data for other endpoints are adequate.

Environmental Fate. These endpoints are adequately addressed for the purposes of the HPV Challenge Program. While the fugacity models are not designed for compounds that are solids in the environment, the predictions of the fugacity model are consistent with the low solubility and volatility of these compounds and are adequate for the endpoint.

Health Effects. It is not clear how the proposed 7-day repeated-dose bridging study would demonstrate that the dissociation products data are representative of aluminum stearates toxicity. Aluminum toxicity is well characterized in the scientific literature and a toxicological profile on aluminum was published by the US Department of Health and Human Services in 1999 (ATSDR). Further, under 40 CFR § 180.910, stearic acid is exempt from the requirement of tolerance (i.e. is designated as 'minimal risk'), obviating the need for further testing under that authority. EPA does not support further testing for mammalian toxicity endpoints for the purposes of the HPV Challenge Program, despite the data gaps.

Ecological Effects. The submitter proposed testing aluminum distearate for aquatic toxicity using a daphnia reproduction study. EPA questions whether the chemical will be toxic in a chronic test. The very low estimated water solubility value and the high log Kow suggest that no further testing is needed for the purposes of the HPV Challenge Program.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. We ask that the Coalition advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
J. Willis